REMARKS

Claims 3-6 are pending in the instant application. Claims 3-6 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

I. **Rejection of Claims 3-6 under 35 U.S.C. § 112, second paragraph**

Claims 3-6 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the metes and bounds for the phrase "under stringent conditions" are not clear.

Applicants respectfully disagree.

In accordance with MPEP § 2173, the primary purpose of the requirement of definiteness of claim language is to ensure that the scope of the claimed invention is clear so that the public is informed of the boundaries of what constitutes infringement of the patent. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in that pertinent art at the time the invention was made. Only a reasonable degree of particularity and distinctness is required. MPEP § 2173.01. Further, the MPEP and the case law are clear; when reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph.

Claims of the instant application are drawn to methods for determining in cells, tissues or bodily fluids of a patient levels of Ovr107 comprising a polynucleotide sequence of SEQ ID NO:1 or a polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO: 1.

Methods for assessing whether a polynucleotide hybridizes under stringent conditions are well known to those of skill in the art and set forth in great detail in standard reference texts such as Sambrook et al. 1989 (Molecular Cloning, A Laboratory Manual, 2nd Edition, Cold Spring Harbor Press, Cold Spring Harbor). Such methods can be performed routinely by those of

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

skill in the art to assess whether or not a polynucleotide from a cell, tissue of bodily fluid of a patient hybridizes under stringent conditions to SEQ ID NO:1 and thus falls within the scope of the claimed method.

Further, definitions from two online dictionaries which were available prior to the filing date of the instant application for the term hybridization stringency are also being provided herewith. Both definitions require that the percentage of matching nucleotides be 70% or greater for stringent hybridization to occur. Accordingly, one of skill in the art can also routinely assess whether or not a polynucleotide falls within the scope of the instant claims by determining whether the sequence has 70% or greater identity with SEQ ID NO:1.

Thus, the claims, as amended are definite when read in light of the teachings of the prior art and what is well known by those of skill in the art. Further, the claims when read as a whole apprise one of ordinary skill in the art of their scope, thus meeting the requirements of 35 U.S.C. § 112, second paragraph.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is therefore respectfully requested.

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

II. Rejection of Claims 3-6 under 35 U.S.C. § 112, first paragraph

Claims 3-6 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner has acknowledged that the specification provides evidence for the species SEQ ID NO:1 being a cancer marker. However, the Examiner suggests that one cannot predict the types of additional species that could be used as cancer markers based upon this one species. Further, the Examiner suggests that possession of a single species is not sufficient to reasonably convey possession of the entire genus of nucleic acids recited as "polynucleotide which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:1."

Applicants respectfully traverse this rejection.

In accordance with MPEP § 2163.02, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means such as words, structures, figures, diagram and formulas that fully set forth the claimed invention. In the instant

application, Applicants have set forth the entire sequence of SEQ ID NO:1. Further, at page 3 of the application, Applicants specifically teach that levels of a polynucleotide which is capable of hybridizing under stringent conditions to the antisense sequence of SEQ ID NO:1 can also be detected. As discussed in Section I, *supra*, the phrase "stringent hybridization" is defined by those skilled in the art as requiring the percentage of matching nucleotides be 70% or greater. Thus, the instant specification clearly provides the required definitive structural features that the claimed polynucleotides have at least 70% identity to SEQ ID NO:1 so that one of skill in the art can predictably identify molecules as being encompassed by the claims. Accordingly, contrary to the Examiner's suggestion, the instant claims meet the requirements of 35 U.S.C. § 112, first paragraph.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

Attorney Docket No.: DEX-0115
Inventors: Salceda et al.
Serial No.: 09/717,883
Filing Date: November 21, 2000
Page 7

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

Kathleen A. Tyrrell
Registration No. 38,350

Date: January 22, 2002

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515

Received from <8568101454> at 1/22/03 4:27:55 PM [Eastern Standard Time]

hybridisation stringency

<molecular biology> The percentage of nucleotides which must match on two unrelated single-stranded nucleic acid molecules before they will base pair with each other to form a duplex, given a certain set of physical and chemical conditions.

The hybridisation stringency is used to determine when a hybridisation probe and a target nucleic acid will come together, and can be set by the researcher by varying the conditions. In general, if the percentage of matching nucleotides is lower than 70 percent, the two single-stranded nucleic acid molecules are considered nonhomologous and any hybridisation is considered nonstringent.

(13 Oct 1997)

Previous: hybrid DNA, hybrid dysgenesis, hybrid enzyme, hybrid inviability, hybridisation
Next: hybridism, hybridization, hybrid molecule, hybrid name, hybridoma

Published at the Dept. of Medical Oncology, University of Newcastle upon Tyne
© Copyright 1997-2002 - The CancerWEB Project. All Rights Reserved.

BioTech LIFE SCIENCE DICTIONARY **Search Results**

Search Terms: AND Search Definitions:

Contains this Begins with this

Find Words! Clear Form

Searching Category	User input query
Searched Word	hybridization
Number of Results	14

1. 1 colony hybridization
Definition:
A genetics lab technique used to identify which colonies of bacteria on an agar plate contain a particular sequence of DNA or a particular gene. The technique involves pressing a nylon or nitrocellulose membrane onto the plate so that each colony contributes a small smudge of itself to the membrane, then treating the membrane with chemicals and heat, then washing the membrane with a labeled probe to find the specific DNA sequence. The smudges which are indicated by the probe are then compared back to the colonies on the agar plate. This technique is often used in conjunction with experiments involving the making of genomic libraries.

2. competition hybridization
Definition:
A lab technique used to determine how similar two strands of single-stranded nucleic acids are to each other by putting them with a third strand (called a standard) and observing how well they can bond with each other to become double-stranded (how well they hybridize).

3. cross-hybridization (cross hybridization)
Author: Susan A.Hagedorn
Definition:
The hydrogen bonding of a single-stranded DNA sequence that is partially but not entirely complementary to a single-stranded substrate. Often, this involves hybridizing a DNA probe for a specific DNA sequence to the homologous sequences of different species.

4. DNA hybridization
Definition:
A lab technique used to find out how closely related two or more separate strands of DNA from different species are to each other. The technique involves radioactive labeling.

5. DNA-DNA hybridization

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

Definition:

A type of hybridization. In this case, a strand of DNA is joined with a complementary strand of RNA to form a double-stranded molecule (or one which is partly double-stranded, if one of the original single strands is shorter than the other).

6. FISH (fluorescence in situ hybridization)

Definition:

A physical mapping approach that uses fluorescent tags to detect hybridization of probes with metaphase chromosomes and with the less-condensed somatic interphase chromatin.

7. hybridization

Definition:

1. The process of joining two complementary strands of DNA or one each of DNA and RNA to form a double- stranded molecule.
2. The mating of individuals from different species or sub-species.

8. hybridization stringency

Definition:

The percentage of nucleotides which must match on two unrelated single-stranded nucleic acid molecules before they will base pair with each other to form a duplex, given a certain set of physical and chemical conditions. The hybridization stringency is used to determine when a hybridization probe and a target nucleic acid will come together, and can be set by the researcher by varying the conditions. In general, if the percentage of matching nucleotides is lower than 70 percent, the two single-stranded nucleic acid molecules are considered nonhomologous and any hybridization is considered nonstringent.

9. in situ hybridization

Definition:

Use of a DNA or RNA probe to detect the presence of the complementary DNA sequence in cloned bacterial or cultured eukaryotic cells.

Also used for locating genes on chromosomes. The process is:

1. Prepare microscope slide with cells in metaphase of mitosis.
2. Treat slide with a weak base. Thus denaturing the DNA.
3. Pour radioactively labeled probe onto the slide.
4. Expose slide to photographic emulsion for a few days or weeks.
5. Develop emulsion.

10. introgressive hybridization

Definition:

The incorporation into a population's gene pool of genes from a different species.

11. Northern blot (Northern hybridization, Northern blotting)

Definition:

A technique similar to Southern blotting, though it is used for RNA. In this technique, RNA fragments are transferred from an agarose gel to a nitrocellulose filter, where the [illegible] dioactive probe.

Received from < 8568101454 > at 1/22/03 4:27:55 PM [Eastern Standard Time]

12. **probe (hybridization probe)**
Definition:

A single-stranded nucleic acid molecule with a known nucleotide sequence which is labeled in some way (for example, radioactively, fluorescently, or immunologically) and used to find and mark certain DNA or RNA sequences of interest to a researcher by hybridizing to it.

13. **Southern blot (Southern hybridization, Southern blotting)**
Definition:

A technique used for searching for a specific DNA fragment. The process is as follows:

1. Separate DNA fragments by gel electrophoresis
2. change pH of gel to basic, thus allowing disruption of H-bonds
3. blot gel with nitrocellulose paper
4. heat paper so as to fix DNA fragments
5. probe with labeled messenger RNA or cDNA
6. wash
7. complementary mRNA/cDNA fragments will have hybridized.

14. **Western blot (Western hybridization, Western blotting)**
Definition:

A technique similar to Southern blotting, though it is used for proteins.

END

All entries Copyright 1995-98 by their respective authors or, if no author is listed, by BioTech Resources and Indiana University